MAR 2 6 2002

Clinicon CORPORATION
5825 AVENIDA ENCINAS ♦ CARLSBAD, CA 92008

K014236

510(k) Summary

Submitter:	Clinicon Corporation 5825 Avenida Encinas Carlsbad, CA 92008
Contact person:	Sean M. Curry 16787 Bernardo Center Drive, Suite A San Diego, CA 92128
Phone:	(858) 675-8200
FAX:	(858) 675-8201
Proprietary name:	Clinicon WaveGuide Platform with Interconnect for Luxar Accessories
Common name:	CO_2 Laser Powered Surgical Instrument
Classification:	878.4810
Product Code:	GEX
Classification name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.

Substantial equivalence claimed to:

K992472, Clinicon's SureGuide CO2 Laser Beam Delivery System
K960475, Modified Luxar LX-20

Description:

The Clinicon WaveGuide Platform (K992472, SureGuide CO2 Laser Beam Delivery System now marketed as Clinicon WaveGuide Platform) is an accessory for CO_2 laser systems. Its two primary components are a laser system interface adapter and a fiber cable assembly consisting of a hollow silica fiber having an internal coating that reflects and propagates CO_2 laser energy and a flexible protective outer cover.

The WaveGuide CO_2 Fiber Cable has FSMA 905 series fiber optic connectors on each end and may be used with CO_2 laser systems that provide such connectors between the laser system and various beam delivery accessories.

The Clinicon Interconnect (Distal Adapter) is an accessory to the WaveGuide Platform that duplicates the termination end & laser beam characteristics of the Standard Luxar

Fiber. This allows Luxar accessories to be attached to the WaveGuide Platform and used in the same manner.

Intended use:

The intended use of the Clinicon WaveGuide Platform is to deliver carbon dioxide laser energy from a CO_2 laser source to a CO_2 laser accessory, with minimal beam degradation. The waveguide platform can be used with various manufacturers' CO_2 lasers and laser accessories, including Clinicon accessories. The specific indications are dependent upon the cleared indications for use of the laser system and laser accessories to which the waveguide platform is attached.

The Clinicon Interconnect (Distal Adapter) enables Luxar accessories that are designed to be used with the standard Luxar fiber cables to be connected with the Clinicon WaveGuide Platform.

Summary of technological characteristics:

The Clinicon WaveGuide Platform is an accessory for CO_2 laser systems. Its two primary components are a turret adapter and a fiber cable assembly. A secondary component is the Interconnect accessory.

The fiber cable assembly consist of a hollow silica fiber with an internal coating that reflects and propagates the CO_2 laser energy and a flexible protective outer covering. The fiber cable has a fiber optic connector on each end and may be used with CO_2 laser systems that provide such connectors between the laser system and various beam delivery accessories. The fiber cable is available in various standard lengths between 0.5 m and 3.0 m, and functions over the wavelength range of 9 – 11 μm.

The Turret Adapter is the interface between the fiber cable and the CO_2 laser system, and houses a focusing lens to align the beam from the CO_2 laser system into the waveguide.

The Interconnect duplicates the distal termination end and laser beam characteristics of the Standard Luxar Cables. The Clinicon Interconnect contains a segment of the same coherent waveguide used throughout the Clinicon Waveguide Platform. Uniquely in the Interconnect, however, this waveguide segment is held in a manner that "scrambles" the spatial coherence of the input laser beam, so that the output laser beam is spatially incoherent. The particular distortion has been chosen so that the output of the Clinicon Fiber Cable with the Clinicon Interconnect has the same beam divergence and multimode character as does the output of the Luxar Fiber [cable]. This allows Luxar accessories to be used with the Clinicon Fiber Cable plus Clinicon Interconnect.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2002

Clinicon Corporation
c/o Mr. Sean Curry
Certified Software Solutions, Inc.
16787 Bernardo Center Drive, Suite A
San Diego, CA 92128

Re: K014236
Trade/Device Name: Clinicon WaveGuide Platform with Interconnect for Luxar Accessories
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 21, 2001
Received: December 26, 2001

Dear Mr. Curry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K014236

Device Name:

Indications for Use:

The intended use of the Clinicon WaveGuide Platform is to deliver carbon dioxide laser energy from a CO_2 laser source to a CO_2 laser accessory, with minimal beam degradation. The waveguide platform can be used with various manufacturers' CO_2 lasers and laser accessories, including Clinicon accessories. The specific indications are dependent upon the cleared indications for use of the laser system and laser accessories to which the waveguide platform is attached.

The Clinicon Interconnect enables Luxar accessories that are designed to be used with the standard Luxar cables to be connected with the Clinicon WaveGuide Platform.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K014236

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use_____
(Per 21 CFR 801.109)